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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,686	03/09/2001	Gary Van Nest	377882000900	9981
25226	7590	04/23/2004	EXAMINER	
MORRISON & FOERSTER LLP			BROWN, TIMOTHY M	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	

1648

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,686

Applicant(s)

VAN NEST, GARY

Examiner

Tim Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2003 has been entered.

The objection to claim 11 is withdrawn in response to Applicant's amendment. The art rejections made in the previous Office Action are withdrawn in response to Applicant's amendment. Applicant's arguments are therefore moot in view of the following new grounds of rejection.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation. A number of factors are considered in determining whether undue experimentation is required to practice Applicant's invention. These factors include the nature of the invention and the state of the prior art. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

The nature of Applicant's invention is a method and kit for suppressing respiratory syncytial virus infection in an individual. The invention relies on the administration of an immunostimulatory sequence (ISS) without the coadministration of viral antigen or immunostimulatory cytokine. The prior art teaches eliciting an immune response in an individual through the introduction of an ISS, a viral antigen and a immunostimulatory cytokine. The administration of a viral antigen is critical to the therapeutic use ISSs since an immune response against a viral target requires the introduction of viral antigen. In other words, one would not expect the administration of ISS alone to induce a specific immune response against RSV. Accordingly, Applicant's invention fails disclosure fails to how the administration of an ISS alone would overcome the requirement of the coadministration of viral antigen as known in the prior art.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 1 and 11 recite "wherein the ISS comprises sequence 5'-C, G-3'." The recitation of "5'-C, G-3'" renders the claim indefinite because it is unclear whether Applicant's ISS is directed to a CpG or some other nucleotide motif. If Applicant intended to claim the CpG motif, it is recommended that Applicant replace "5'-C, G-3'" with "CpG."

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6, 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al. (US 6,406,705).

Regarding claims 1-4, 6, 8 and 9, Davis teaches a method for suppressing respiratory syncytial virus infection in an individual comprising administering an ISS to the respiratory tract of said individual (col. 8, lines 56-62; col. 15, line 65; col. 16, line 67; col. 17, line 1; and col. 31, lines 49-60), wherein said ISS is greater than 6 and less than 200 nucleotides in length (col. 4, lines 18-19), wherein neither a viral antigen nor an immunostimulatory cytokine is coadministered with said ISS (col. 3, lines 4-6), and wherein said composition is administered in an amount sufficient to suppress an RSV infection (col. 9, lines 29-32). Davis further teaches performing its method by administering an ISS having the sequence 5'-CACGTTCC-3' (col. 30, line 30). Davis also teaches administering the ISS to the nasal passages and the lungs (col. 31, lines 58-60).

Regarding claim 10, the Examiner submits the limitation "wherein the suppression comprises a reduction of RSV titer in a biological sample from said individual" is inherent to the teachings of Davis. Davis provides that its method can "reduce or eliminate [viral] infection or prevent it from becoming worse" (col. 17, lines 1-3). By necessity, the reduction or elimination

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of RSV infection would result in the reduction of viral titer in the lungs of the infected individual. Accordingly, the reduction of RSV titer recited in claim 10 is inherent to the teachings of Davis.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis.

Davis teaches all the limitations discussed under 1-4, 6 and 8-10. Davis does not expressly teach assembling the ISS sequence into a kit wherein said kit lacks RSV antigen and an immunostimulatory cytokine. However, assembling reagents in preparation for an experiment is well within the knowledge generally available to one skilled in the art. Moreover, assembling reagents ensures that all the components necessary for an experiment are present. Accordingly, it would have been obvious at the time of Applicant's invention to assemble Davis' ISS into a kit in order to facilitate the execution of its method. Note the disclosure of Davis would serve as instructions for administering the ISS sequence.

Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Raz et al. (US 6,589,940) (hereinafter "Raz").

Regarding claim 5, Davis teaches all the limitations discussed under claims 1-4, 6 and 8-10. Davis does not expressly teach an ISS comprising SEQ ID NO:1. However, Raz overcomes this deficiency through its disclosure of a polynucleotide having the sequence of SEQ ID NO:1. At the time of Applicant's invention, it would have been obvious to one of ordinary skill to perform Davis' method using SEQ ID NO:1 in that this sequence is an art recognized equivalent of the polynucleotides taught by Davis. MPEP 2144.06 provides that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 CCPA (1982). In present case, the polynucleotides disclosed by Davis are the functional equivalent of SEQ ID NO:1 in that they each relate to polynucleotides having an immunostimulatory function. Accordingly, at the time of Applicant's invention, it would have been obvious to substitute SEQ ID NO:1 for Davis' immunostimulatory polynucleotides.

Regarding claim 15, the Examiner submits it would have been obvious to arrange the reagents taught by Davis and Raz into a kit as discussed under claims 11-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tmb

Sharon Foley
Patent Examiner, 1600